Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13044

0 - FRONT

[redacted] CFSAN [redacted]

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

For VOLUNTARY reporting by health professionals of adverse events and product problems

CFSAN

See OMB statement on reverse

FDA Use Only — H Pad

Triage unit sequence # 87675

13044

Page 1 of 2

A. Patient information

1 Patient Identifier	2 Age at time of event: / or Date of birth:	3. Sex	4 Weight
[redacted] In confidence	56	☒ female ☐ male	140 lbs or ____ kgs

B. Adverse event or product problem

1 ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2 Outcomes attributed to adverse event (check all that apply)

- ☐ death (mo/day/yr)
- ☐ life-threatening
- ☒ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☐ required intervention to prevent permanent impairment/damage
- ☐ other

3 Date of event (mo/day/yr): 8/3 → 8/5/98

4 Date of this report (mo/day/yr): 8/6/98

5 Describe event or problem

Patient had stable health. Treatment for Depression, Trazodone 150mg at bedtime for 5 years without symptoms, etc. 2 weeks before Hospitalization, patient Purchased Metabolife™ OTC, from Shopping Mall – see separate enclosure for list of ingredients. Took one capsule TID for 2 wks → then Hospitalized for Chest-Pain and elevated Liver Enzymes – SGOT 555 B.li 2.5 Alk ϕ – 250. Chest-Pain evaluation was negative, Hepatic Enzymes were decreasing at discharge – Metabolife stopped. – strongly suspect Adverse Drug Reaction to Metabolife

6 Relevant tests/laboratory data, including dates

Tests 8/3 → 8/5/98
SGOT 555 on 8/3 ; 225 on 8/5
Bili 1.5 on 8/3 ; 2.5 on 8/5
Alkaline Phosphine 205 → 275
EKG, CXR, Cardiac Enzymes ch were negative.

7 Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Depression → 5 yrs of treatment with Trazodone / Prozac
HRT with Premarin 0.625mg
non-smoker and drinker.
Renal Function normal.
White Female; no allergies.

C. Suspect medication(s)

1 Name (give labeled strength & mfr/labeler, if known)

#1 OTC Product – Metabolife™ Ind. Dist. [redacted] (original) Phone # [redacted]

#2

2 Dose, frequency & route used

#1 one cap TID

#2

3 Therapy dates (if unknown, give duration) (from/to (or best estimate))

#1 approximately 7/20 → 8/2/98

#2

4 Diagnosis for use (indication)

#1 OTC – Marketed as 'Diet Pill'

#2

5 Event abated after use stopped or dose reduced

#1 ☒ yes ☐ no ☐ doesn't apply

#2 ☐ yes ☐ no ☐ doesn't apply

6 Lot # (if known)

#1 Not Known

#2

7 Exp. date (if known)

#1

#2

8 Event reappeared after reintroduction

#1 ☐ yes ☐ no ☒ doesn't apply

#2 ☐ yes ☐ no ☐ doesn't apply

9 NDC # (for product problems only)

– –

REC'D. AUG 06 1998

10 Concomitant medical products and therapy dates (exclude treatment of event)

REC'D. AUG 06 1998

MEDWATCH CTU

D. Suspect medical device

1 Brand name

2 Type of device MEDWATCH CTU

3 Manufacturer name & address

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other

5 Expiration date (mo/day/yr)

6. model # HF-2

catalog #

serial #

lot #

other ID #

7 If implanted, give date (mo/day/yr)

8 If explanted, give date (mo/day/yr)

RECEIVED AUG 14 1998

9 Device available for evaluation? ☐ yes ☐ no (Do not send to FDA)

returned to manufacturer on (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1 Name, address & phone #

[redacted]

2 Health professional? ☒ yes ☐ no

3. Occupation: Physician

4 Also reported to
- ☐ manufacturer
- ☐ user facility
- ☒ distributor

5 If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☐

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

CTU 87675

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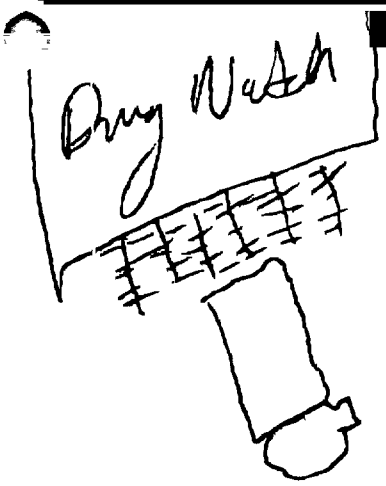
[redacted]

Metabolife™ Ind. Dist

[redacted]

[redacted]



Proprietary Blend 728mg

Guarana Concentrate (seed)
(40mg naturally-occuring caffeine)

Ma Huang Concentrate (aerial part)
(12mg naturally-occuring ephedrines)

Bee Pollen
Ginseng (root)
Ginger (root)
Lecithin
Bovine Complex
Damiana (leaf)
Sarsaparilla (root)
Golden Seal (aerial part)
Nettles (leaf)
Gotu Kola (aerial)
Spirulina Algae
Royal Jelly

87675

Adverse Event Questionnaire

Complaint Number: HFS-636 Project # 13044 KAN-00 ASSIGN. # 98-0215 **Investigator:** RANDY BAXTER, CSO [redacted]

Consumer Information

Date of Report: 08/06/98 MM/DD/YY

Initial Report Source: ☐ORA Consumer Injury ☐Telephone ☐Correspondence ☒MedWatch ☐USP ☐PQRS ☐Poison Control ☐CDC [redacted]

Name: [redacted] Gender: ☒F ☐M Age: 55 yo (DOB [redacted])

Race: ☒1-White ☐2-Black ☐3-Asian/Pacific Islander ☐4-Native American ☐5-Hispanic ☐8-Other_____ ☐9-Unknown

Information on Adverse Event

Date of Adverse Event: 8/03-05/98
Previous Adverse Effects to Product Type: ☐Yes ☒No

Give the site of consumption/ingestion (e.g. home, restaurant, office): HOME (approx. 2 wks on Metabolife)

The following information relates to the consumers' use of the product.

Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): CHEST PAIN AND ELEVATED LIVER ENZYMES following 2 weeks of taking product * HOSPITALIZED @ [redacted] 8/03/98

How long did the symptoms last

Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). ONE capsule/day for 2 weeks

List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: PREMARIN (Estrogen replacement) for [redacted] (non-[redacted]/drinker) reportedly a "light" smoker PROZAC for DEPRESSION NO KNOWN ALLERGIES

Did event abate after use of suspected product stopped or dose reduced: ☒Yes ☐No ☐Unknown

Did symptoms reoccur after reintroduction of suspected product: ☐Yes ☐No ~~☒Unknown~~ ☒Not Applicable

Did symptoms reoccur after using other products with the same ingredients: ☐Yes ☐No ☐Unknown ☒Not Applicable

Medical Information

[redacted]

Was a health care provider seen?: ☒Yes ☐No

Give health care provider's name, address and telephone number: [redacted]

Occupation of Health Care Provider: ☒MD ☐Osteopath ☐Naturopath ☐Nurse ☐Pharmacist ☐Other (specify) _____

What medical tests were performed and what were the results? Dr. [redacted] comment on Medwatch form

What was the medical diagnosis? * "strongly suspect adverse drug reaction to Metabolife" *

What treatment(s) was given (e.g., drugs, other)? no drugs

Were there any preexisting condition(s)/treatment(s)? PROZAC/depression PREMARIN/[redacted] estrogen replacement (also taking TRAZODONE) (If YES, list them including allergies, and chronic diseases): ☒Yes ☐No

* Medications: PREMARIN 0.625 mg q.d.
Desyrel 150 mg h.s.
PROZAC 20 mg two tablets q.d. * Also taking TRAZODONE in comb. w/ PROZAC for treatment of Depression. RDBaxter

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Product Category

1. Adverse event attributed to:
   ☐**Medical Food** (under medical supervision) ☐**Infant Formula**
   ☒**Dietary Supplement** (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands; garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients.)
   ☐**Other** (traditional food) _____

   * Ma Huang Concentrate
   * Bovine Complex
   * Ginseng

Other Product Problems

2. ☐Foreign Object
(specify):_____

3. ☐Other (specify):
_____

Information on Suspected/Alleged Product

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):
☐Check here if ingredients are unknown Vit E; Magnesium; Zinc; Chromium Picolinate GUARANA concentrate; Ginseng; Bovine complex; damiana leaves; sarsparilla root; Nettles; goldseal; kolafukola; spirunina algae; Bee Pollen; Royal jelly * Ma Huang Concentrate; Ginger; Lecithin; Methocel; cRoscarmelose sodium;

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

☐Aspartame
☐Monosodium Glutamate
☐Sulfite
☐Other_____
☐Unknown

☐Color Additive (please specify) _____

Is the product label available, if yes submit a quality copy along with this questionnaire: ☐Yes ☐No ☐Unknown Product Sample Available: ☐Yes ☐No ☐Unknown

Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records) * Med. Recds. Attached to summary report - RDB

Death: ☐Yes ☒No

Life-Threatening: ☒Yes ☐No

Hospitalization: ☒Yes ☐No (if YES, indicate if initial or prolonged) _____

Required intervention to prevent permanent impairment/damage: ☐Yes ☐No * stopped taking Metabolife

Did the adverse event result in a congenital anomaly: ☐Yes ☒No

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Recd 11/4/98

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
KANSAS CITY DISTRICT

MEMORANDUM

November 02, 1998

To: Bridgette Wallace, CfSAN Adverse Reaction Monitoring System (ARMS) Monitor, HFS-636

From: Randy D. Baxter, CSO, [redacted] Resident Post

Subject: Follow-up to HFS-636 project #13044/KAN-DO Assignment #98-0215 (Metabolife).

On 10/23/98 I obtained authorization for release of medical records from Ms. [redacted] of [redacted] [redacted] said she had been taking Metabolife dietary supplements for two weeks prior to the onset of her illness.

Ms. [redacted] initially went to [redacted] 8/03/98 complaining of chest and back pain. Following an "abnormal" EKG the patient was immediately transported to [redacted] via ambulance for treatment. While in the ER she was noticed to have an abnormal liver function test and was hospitalized for evaluation.

The physician's impression is as follows: "Hepatitis of unknown cause, possibly related to over-the-counter medicines with multiple herbal ingredients, including Ma Huang and guarana and several other medicines as mentioned in the History of Present Illness.", see Exhibit #2, page 4. Dr. [redacted] also states "It was felt likely that she suffered liver injury from an OTC preparation that she bought two weeks prior to admission for weight loss.", see Exhibit 2, page 1.

Four pages of medical records provided by [redacted] are attached as Exhibit 1. Exhibit 2 consists of 31 pages of records provided by [redacted] I also visited a local Metabolife Distributor and was provided a leaflet regarding the product and an empty Metabolife bottle. An Adverse Event Questionnaire (IOM Ex 910-D) was completed and is also attached.

Randy Baxter, Investigator
[redacted] Resident Post

attachments: